

CLAIMS

I claim:

1. A method for monitoring the effectiveness of a regimen for treatment of a disease, comprising:

5 (i) obtaining, from a subject, one or more measurements selected from the group consisting of self-reported data and behavioral, genetic, neurological, biochemical and physiological measurements;

10 (ii) treating said subject, or a different subject, with said regimen for a selected period of time;

15 (iii) obtaining from a subject who has been treated with the regimen, one or more measurements selected from the group consisting of self-reported data and behavioral, genetic, neurological, biochemical and physiological measurements;

20 (iv) determining changes in the measurements induced by the regimen, by comparing the measurements obtained in (i) with the measurements obtained in (iii);

25 (v) comparing said measurements or changes in the measurements, or both, to a signature, said signature representing probability relationships between one or more predictor variables and one or more clinical outcomes for said disease; and

30 (vi) determining, from the comparison in step (v), a probability that continued treatment of the subject with the regimen will result in a favorable clinical outcome;

wherein the identities of the predictor variables are determined by correlating previously-obtained clinical outcomes with previously-obtained measurements selected from the group consisting of self-reported data and behavioral, genetic, neurological, biochemical and physiological measurements, and mathematical combinations thereof, said correlations being derived by using at least one automated non-linear algorithm.

30 2. The method of claim 1, wherein the disease is ocular disease, the clinical outcome is an increase in visual acuity, and the measurement is a measure of retinal thickness..

3. The method of claim 2, wherein the disease is macular disease.

4. The method of claim 2, wherein the measure of retinal thickness is obtained by a means selected from the group consisting of confocal scanning laser ophthalmoscopes, optical coherence tomography scanners, and scanning retinal thickness analyzers.
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5. The method of claim 3, wherein the measure of retinal thickness is obtained by a means selected from the group consisting of confocal scanning laser ophthalmoscopes, optical coherence tomography scanners, and scanning retinal thickness analyzers.
- 10 6. The method of claim 2, wherein the treatment regimen comprises administration of an anti-inflammatory corticosteroid.
7. The method of claim 3, wherein the treatment regimen comprises administration of an anti-inflammatory corticosteroid.
- 15 8. The method of claim 4, wherein the treatment regimen comprises administration of an anti-inflammatory corticosteroid.
9. The method of claim 5, wherein the treatment regimen comprises administration of an
- 20 anti-inflammatory corticosteroid.
10. The method of claim 6, wherein the anti-inflammatory corticosteroid is administered via an intraocular implant.
- 25 11. The method of claim 7, wherein the anti-inflammatory corticosteroid is administered via an intraocular implant.
12. The method of claim 8, wherein the anti-inflammatory corticosteroid is administered via an intraocular implant.
- 30 13. The method of claim 9, wherein the anti-inflammatory corticosteroid is administered via an intraocular implant.

14. The method of claim 10, wherein the corticosteroid is fluocinolone acetonide or triamcinolone acetonide.

5 15. The method of claim 11, wherein the corticosteroid is fluocinolone acetonide or triamcinolone acetonide.

16. The method of claim 12, wherein the corticosteroid is fluocinolone acetonide or triamcinolone acetonide.

10 17. The method of claim 13, wherein the corticosteroid is fluocinolone acetonide or triamcinolone acetonide.

18. A pharmaceutical product for treatment of an ocular disease, comprising:

(i) a drug substance indicated for treatment of a macular disease; and

15 (ii) instructions for monitoring the effectiveness of a treatment regimen according to the method of any one of claims 2-17;

wherein the treatment regimen comprises administration of the indicated drug substance.

19. A pharmaceutical product according to claim 18 wherein the drug substance and the 20 instructions are packaged together.

20. A pharmaceutical product according to claim 18, further comprising means for accessing a database containing one or more signatures representing probability relationships between changes measurements selected from the group consisting of self-reported data, behavioral, neurological, biochemical, or physiological responses, and clinical outcomes for macular disease.

21. A pharmaceutical product according to claim 19, further comprising means for accessing a database containing one or more signatures representing probability relationships between changes measurements selected from the group consisting of self-reported data, behavioral, neurological, biochemical, or physiological responses, and clinical outcomes for macular disease.

22. A pharmaceutical product according to claim 18, wherein at least one of the measurements is a measurement of retinal thickness.

23. A pharmaceutical product according to claim 19, wherein at least one of the measurements is a measurement of retinal thickness.

5 24. A pharmaceutical product according to claim 20, wherein at least one of the measurements is a measurement of retinal thickness.

25. A pharmaceutical product according to claim 21, wherein at least one of the measurements is a measurement of retinal thickness.

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26. A pharmaceutical product according to claim 22, wherein the clinical outcome is an improvement in visual acuity.

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26. A pharmaceutical product according to claim 23, wherein the clinical outcome is an improvement in visual acuity.

20 16 26. A pharmaceutical product according to claim 24, wherein the clinical outcome is an improvement in visual acuity.

26. A pharmaceutical product according to claim 25, wherein the clinical outcome is an improvement in visual acuity.

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27. A method for treating an ocular disease, comprising administering a drug indicated for treatment of an ocular disease, and monitoring the effectiveness of said administration by the method of any of claims 2-17.

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28. A method for conducting a drug discovery business, comprising:

- (i) obtaining, from a test animal or from stored data, one or more measurements selected from the group consisting of behavioral, neurological, biochemical and physiological measurements;
- (ii) treating said test animal with a test compound for a selected period of time;

(iii) obtaining, from a test animal treated with the regimen, one or more measurements selected from the group consisting of behavioral, neurological, biochemical and physiological measurements;

5 (iv) determining changes in the measurements induced by the regimen, by comparing the measurements obtained in (i) with the measurements obtained in (iii);

(v) comparing said measurements or changes in the measurements, or both, to a signature, said signature representing probability relationships between one or more predictor variables and one or more clinical outcomes for said disease;

10 and

(vi) determining, from the comparison data of step (ii), the suitability of further clinical development of the test compound;

wherein the identities of the predictor variables are determined by correlating pre-determined physiological states, or responses to known drugs, with previously-obtained measurements selected from the group consisting of self-reported data and behavioral, genetic, neurological, biochemical and physiological measurements, and mathematical combinations thereof; said correlations being derived by using at least one automated non-linear algorithm.

31 29. The method of claim 28, further comprising conducting therapeutic profiling of a test
20 compound determined to be suitable for further clinical development for efficacy and toxicity in animals.

33 30. The method of claim 28, further comprising preparing a structural analogue of a test compound determined to be suitable for further clinical development, and conducting
25 therapeutic profiling of said analogue for efficacy and toxicity in animals.

34 31. The method of claim 29 or claim 30, further comprising licensing a test compound determined to be suitable for further clinical development, or an analog thereof, to another business for clinical trials in human subjects.